510(k) Summary

MAY - 9 2008

Name:	Cook Ireland Ltd
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Contact Persons:	Emmett Devereux, Quality & Regulatory Manager Noreen Barry, Regulatory Affairs Specialist
Phone:	353 61 334440
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Date:	May 8, 2008
Trade Name:	Evolution™ Esophageal Stent System
Common Name:	Esophageal Stent
Classification Name:	Esophageal Prosthesis (21 CFR 878.3610, Product Code: ESW)
Legally Marketed Devices:	Esophageal Z Stent with Dua Anti-Reflux Valve (K011591) Wallstent II Esophageal Prosthesis (K940395) Ultraflex™ Esophageal NG Stent System (K032930).
Description of the Device:	Stent Description: This flexible, self-expanding stent is constructed of nitinol wire with a silicone cover. The total length of the stent is indicated by radiopaque markers on the inner catheter,

	indicating the actual length of the stent at nominal stent diameter. There is a lasso at the proximal end of the stent whose purpose is to reposition the stent as needed. Introducer System Description: The stent is mounted on an inner catheter, which accepts a 0.035 inch guidewire and is constrained by an outer catheter. A pistol-grip delivery handle allows stent deployment or recapture.
Indications for use:	This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.
Comparison of Characteristics:	The proposed device is substantially equivalent to the currently marketed devices, the Esophageal Z Stent with Dua Anti-Reflux Valve (K011591); the Wallstent II Esophageal Prosthesis (K940395); and the Ultraflex™ Esophageal NG Stent System (K032930).
Performance Data:	Non clinical testing was carried out to determine the equivalence of the Evolution™ Esophageal Stent System to the predicate devices and to verify the safety and effectiveness of the device. The following is a summary of the testing carried out: deployment force testing, expansion force testing, compression force testing, dimensional testing, corrosion testing and tensile strength testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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Ms. Noreen Barry
Regulatory Affairs Specialist
Cook® Ireland Ltd.
O'Halloran Road, National Technology Park
Limerick
IRELAND

Re: K080359
Trade Device/Name: Evolution™ Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: February 7, 2008
Received: February 11 2008

Dear Ms. Barry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K080359

Device Name: Evolution™ Esophageal Stent System

Indications for Use:

This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K080359

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)